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APPLICATION NO. 09/290,798	FILING DATE 04/13/99	FIRST NAMED INVENTOR HELLSTRUM	ATTORNEY DOCKET NO. 30436.33USC1
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EXAMINER BANSAL, G
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ART UNIT 1642	PAPER NUMBER 12
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DATE MAILED: 04/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/290798

Applicant(s)

Hellsheimetal

Examiner

Egathe Bansal

Group Art Unit

1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 1/23/01
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 59-65, 71, 84, 93 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 59-65, 71, 84, 93 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1642

### DETAILED ACTION

1. Applicant's amendment filed January 23, 2001 (Paper No:11/C) is acknowledged. Accordingly, claim 59 is amended and claims 45-58, 66-70, 72-83, 85, 87-92 are canceled without prejudice, and claim 93 is added.

Claims 59-65, 71, 86, 93 are being examined.

2. Applicant's election with traverse of Group II (claims 59-65, 71 and 86) in Paper No. 11/C is acknowledged. The traversal is on the ground(s) that Groups II and IX do not need to be placed into separate groups because there is not an undue burden to search the two groups. This is not found persuasive because restriction groups are not determined solely based on burden of search but also based on the subject matter and classification, and as to whether the inventions belong to patentably distinct subject matter. In this case they do differ, as was set out in the last office action.

The requirement is still deemed proper and is therefore made FINAL.

### *Double Patenting*

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1642

4. Claims are 59, 60-65, 71, 86, 93 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5, 980, 896. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are a species of antibody used in making the immunoconjugate that render the genus obvious.

*Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 59-65, 71, 86, 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abe et al (1986), Kim et al (1986) and Hellstrom et al (1986). *References are cited in IDS.*

The claims are drawn to immunoconjugate comprising an antibody that binds to a Lewis Y antigen and conjugated to a therapeutic agent. Further claims specify the therapeutic agents. Abe et al teach a monoclonal antibody AH6 in that it reacts with LeY (a fucosylated Lewis Y antigen), and that the antibody was useful as a diagnostic agent for colon cancer. Abe et al did

Art Unit: 1642

not specifically teach making a conjugate of antibody and a therapeutic agent. Kim et al also teaches the same antibody of Abe et al and that the LeY structures detected this way are important markers of malignancy and premalignancy that maybe clinically useful in the diagnosis and perhaps management of patients with colorectal cancer. Hellstrom et al also teach evaluating 10,000 Mabs for reactivity with lung cancer and that two of them were selected for preclinical testing in view of their high level of tumor selectivity. Hellstrom et al or Kim et al also do not specifically teach conjugates. Oldham et al teaches (pgs 13-14) that monoclonal antibodies were extremely useful in the diagnosis and treatment of cancers and that antibody immunoconjugates are ideal for this purpose. Schlom et al also teach the use of monoclonal antibodies as immunoconjugates for the specific delivery of therapeutic agents (see page 115). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Abe et al, Kim et al, Hellstrom et al in using antibodies that specifically bind to LeY antigens with the teachings of Schlom et al and Oldham et al to make immunoconjugates for the diagnosis and therapeutic purposes. Furthermore, it also would have been obvious to one of ordinary skill in the art at the time of invention to make immunoconjugates as the art of "magic bullets" was well known, and that monoclonal antibodies had high specificity to target antigens that was put to use for selective targeting of therapeutic agents. One would have been motivated to do so based on a reasonable expectation of success that has been provided amply in the references of Oldham et al and Schlom (which also provide many cross references for specific methodologies of making conjugates).

7. No claim is allowed.

8. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.


Art Unit: 1642

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308- 4995.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 6, 2001

  
**GEETHA P. BANSAL**  
**PRIMARY EXAMINER**